DETAILED ACTION

Applicant's response and amendments dated April 12, 2011, to the Office action dated January 12, 2011, are acknowledged. Claims 11, 13, 15-18, 26, and 27 are currently amended. Claims 11-18 and 20-27 are pending in the application and under current examination.

As noted in the previous Office action, claims 11-18 and 20-27 are not entitled to the benefit of Application Nos. 10/152,924 and 09/968,154, and therefore the effective filing date of these claims is February 27, 2004, the actual filing date of the instant application.

The claim rejections made under 35 U.S.C. § 112 Second Paragraph indicated in the previous Office action are withdrawn in view of applicant's amendments to the claims.

The claim rejections made under 35 U.S.C. § 103 indicated in the previous Office action are maintained for the reasons provided herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-18 and 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammons et al. (WO 03/028776 A1; published April 10, 2003; of

record) in view of Klofta et al. (US 2002/0165508 A1; published November 7, 2002; of record).

Claim 11 encompasses a method for preparing a lotion for reliable high speed processing onto a substrate, the method comprising the steps of: (a) providing a carrier system; (b) mixing a premix solution comprising niacinamide and a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof, at a temperature of at least 35 degrees C; and (c) milling the premix solution into the carrier system at a temperature of at least 35 degrees C to disperse the premix solution until an average droplet diameter of the dispersed premix solution is less than 100 microns to form said lotion.

Hammons et al. disclose a lotion composition applied to a catamenial device such as a sanitary napkin (abstract; page 1, line 10) wherein the lotion composition is formulated by combining a carrier or carrier system with skin treatment agents (page 14, lines 10-20). The skin treatment agents include niacinamide, hexamidine, zinc oxide, and combinations thereof (page 6, lines 21-29). The niacinamide skin treatment agent provides for skin conditioning benefits as well as providing for increased efficacy of the skin treatment agents in controlling skin disorders (page 9, line 26 to page 10, line 2). Glycerine may optionally be added as a dispersing agent for the niacinamide and as a skin conditioning agent and for skin emolliency benefits such as smooth, soothing, and soft feeling skin (page 13, lines 19-24). Panthenol may also optionally be added as a skin conditioning agent that provides for skin emolliency benefits that can leave the skin

feeling smooth, soothing, and soft during and after interaction of the skin tissues with skin treatment agents (page 13, lines 1-7).

Examples II, III, and IX of Hammons et al. specifically disclose lotion compositions containing both niacinamide and glycerine (pages 27-28; table 2). The lotion is prepared by first making a carrier system, then mixing the skin treatment agents and any optional ingredients such as optional skin conditioning agents at a temperature of about 80˚C, wherein carrier system, skin treatment agents, and any optional ingredients are processed at a temperature of about 80˚C (page 23, lines 11-23). Examples II-IX are prepared by formulating a premix solution of zinc oxide skin treatment agent and adding the premix to the other skin treatment agents and any optional ingredients such as panthenol and glycerin, or by formulating a skin treatment solution of hexamidine and niacinamide skin treatment agents and any optional ingredients (page 27, lines 3-9). The skin treatment solution is then added to a carrier solution, wherein the skin treatment solution and carrier system is heated while stirring to a temperature of about 80˚C (page 27, lines 9-11). Hammons et al. do not disclose the step of milling the premix solution into the carrier system to disperse the premix solution until an average droplet diameter of the dispersed premix solution is less than 100 microns. However, such was known in the prior art.

Klofta et al. disclose an absorbent product such as a sanitary napkin having a stable skin care composition disposed on a portion of its skin-contacting surface (paragraphs [0002], [0020]). The composition may include emollients or skin protectants such as petrolatum, glycerin, or propylene glycol (paragraphs [0092],

[0093]). Klofta et al. teach, "It is generally known that solid particles in neat form tend to form clumps or agglomerates, bound by static charges, interactions between functional groups, etc. It is often necessary to break up the clumps in order to disperse the particles, to reduce the settling effect, and to deliver skin benefits effectively. The break-up and dispersion can be accomplished by grinding or milling, by incorporation into a composition with agitation, by predispersing in a dispersant mixture, by predissolving in a carrier or by other methods known to persons skilled in the art." (paragraph [0062]). Klofta et al. further teach that various grinding and/or milling techniques known in the art are sometimes used in the predispersing process to break down the particle size and disperse the particles (paragraph [0063]). As an example, Klofta et al. disclose zinc oxide dispersed in a dispersant fluid where the average particle size is about 0.12 microns and the average agglomerate size is about 1.0 microns (paragraph [0064]). Klofta et al. further teach the use of propylene glycol or glycerine as suitable solvents that are well known in the art as additives for lotions and other similar compositions (paragraph [0137]). Klofta et al. thereby cure the deficiency of Hammons et al. by teaching the step of milling during dispersion of a substance in a lotion to be disposed on an absorbent product such as a sanitary napkin in order to break down particle size and disperse the particles, such that the average particle size is about 0.12 microns and the average agglomerate size is about 1.0 microns.

Claim 12 encompasses the method of claim 11, wherein the carrier system comprises petrolatum. Hammons et al. specifically disclose petrolatum as a suitable

carrier (page 15, lines 7-15; Example 1; Table 1). Klofta et al. also specifically disclose the use of petrolatum (Examples 1-6).

Claim 13 encompasses the method of claim 12, wherein the carrier system further comprises fatty alcohols having 12 to 24 carbon atoms, alkyl ethoxylates, fumed silica, talc, bentonites, hectorites, calcium silicates, magnesium silicates, magnesium aluminum silicates, zinc stearates, sorbitol, colloidal silicone dioxides, spermaceti, carnuba wax, beeswax, candelilla wax, paraffin wax, microcrystalline wax, castrol wax, ceresin, esparto, ouricuri, rezowax, polyethylene wax, C12-C24 fatty acids, polyhydroxy fatty acid esters, polyhydroxy fatty acid amides, polymethacrylate polymers, polymethacrylate and styrene copolymers, or combinations thereof. Hammons et al. specifically disclose all of these compounds as suitable carriers (page 14, lines 21-30; page 17, lines 11-19).

Claim 14 encompasses the method of claim 12, wherein the carrier system further comprises a skin treatment active selected from the group consisting of allantoin, aluminum hydroxide gel, calamine, cysteine hydrochloride, racemic methionine, sodium bicarbonate, Vitamin C, serine protease, metalloprotease, cysteine protease, aspartyl protease, peptidase, phenylsulfonyl fluoride, lipase, diesterase, urease, amylase, elastase, nuclease, guanidinobenzoic acid and its salts and derivatives, chamomile, and mixtures thereof. Hammons et al. specifically disclose all of these compounds as suitable skin treatment actives (page 10, line 27 to page 11, line 6). Klofta et al. also specifically disclose skin care ingredients that can be incorporated into the carrier such as allantoin, aluminum hydroxide gel, calamine, cysteine hydrochloride, racemic

methionine, sodium bicarbonate, serine proteases, metalloproteases, cysteine proteases, aspartyl protease, peptidases, lipases, diesterases, ureases, amylases, elastases, and nucleases (paragraphs [0053], [0055], [0057], [0058]).

Claim 15 encompasses the method of claim 11, wherein the solution is mixed at a temperature of at least 50 degrees C. Hammons et al. disclose mixing the skin treatment agents, such as niacinamide, and any optional ingredients, such as glycerin and panthenol, at a temperature of about 80°C (page 23, lines 11-23; page 13, lines 1-7 and 19-24).

Claim 16 encompasses the method of claim 11, wherein the solution is mixed at a temperature of at least 80 degrees C. Hammons et al. disclose mixing the skin treatment agents, such as niacinamide, and any optional ingredients, such as glycerin and panthenol, at a temperature of about 80°C (page 23, lines 11-23; page 13, lines 1-7 and 19-24).

Claim 17 encompasses the method of claim 11, wherein the milling is at a temperature of at least 50 degrees C. Hammons et al. teach that the skin treatment solution is added to the carrier solution at a temperature of about 80°C (page 27, lines 9-11). Furthermore, Klofta et al. specifically disclose use of a mill when adding the predispersion to the petrolatum carrier at a temperature of about 77° C (Example 1; paragraph [0200]).

Claim 18 encompasses the method of claim 11, wherein the milling step continues until the average droplet diameter of the dispersed premix solution is less than 50 microns. Klofta et al. disclose an average particle size of about 0.12 microns

and an average agglomerate size of about 1.0 microns of the dispersed premix (paragraph [0064]).

Claim 20 encompasses a disposable absorbent article comprising a lotion made according to the method of claim 11, wherein said disposable article is selected from the group consisting of diapers, sanitary napkins, panty liners, and incontinence briefs. Hammons et al. specifically disclose application of the lotion to catamenial devices such as sanitary napkins, pantyliners, and sanitary pads (page 4, lines 11-21; Examples II-IX).

Claim 21 encompasses the method of claim 11, wherein said method further comprises the step of spraying, extruding, or slot coating said lotion onto said substrate. Hammons et al. specifically disclose spraying, extruding, or slot coating the lotion onto the substrate (page 22, lines 22-24; Examples III, V, VII, IX).

Claim 22 encompasses the method of claim 11, wherein said niacinamide is acidified niacinamide. Hammons et al. specifically disclose the use of acidified niacinamide (page 10, lines 13-14).

Claim 23 encompasses the method of claim 11, wherein said material of said premix solution is selected from the group consisting of glycerin, propylene glycol, and mixtures thereof. Hammons et al. specifically disclose the use of glycerine in the premix solution (page 13, lines 19-24; Examples II, III, and IX).

Claim 24 encompasses the method of claim 11, wherein said material of said premix solution is glycerin. Hammons et al. specifically disclose the use of glycerine in the premix solution (page 13, lines 19-24; Examples II, III, and IX).

Claim 25 encompasses the method of claim 11, wherein said lotion further comprises chitosan or chitosan derivative. Klofta et al. specifically disclose that the lotion should preferably include a skin care ingredient such as chitosan (paragraph [0059]).

Claim 26 encompasses the method of claim 21, wherein said premix solution is added to the carrier system at a temperature of 60 to 90 degrees C. Hammons et al. teach that the skin treatment solution is added to the carrier solution at a temperature of about 80°C (page 27, lines 9-11). Furthermore, Klofta et al. specifically disclose use of a mill when adding the predispersion to the petrolatum carrier at a temperature of about 77° C (Example 1; paragraph [0200]).

Claim 27 encompasses the method of claim 21, wherein said premix solution is added to the carrier system at a temperature of 70 to 90 degrees C. Hammons et al. teach that the skin treatment solution is added to the carrier solution at a temperature of about 80°C (page 27, lines 9-11). Furthermore, Klofta et al. specifically disclose use of a mill when adding the predispersion to the petrolatum carrier at a temperature of about 77° C (Example 1; paragraph [0200]).

The teachings of Hammons et al. and Klofta et al. are each directed to the formulation of lotions for application to absorbent articles such as sanitary napkins. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine their teachings by using the milling step of Klofta et al. to mix the premix solution and carrier system of Hammons et al, with the predictable result of obtaining a lotion having an average droplet diameter of the dispersed premix

solution of less than 100 microns, with a reasonable expectation of success. A person of ordinary skill in the art would have been motivated to do so to in order to break down the droplet size and disperse the droplets in the lotion, as suggested by Klofta et al.

Response to Arguments

Applicant's arguments in the Remarks dated April 12, 2011, have been fully considered but they are not persuasive. Applicant argues that the previous Office action relies on a conclusory statement that "such was known in the art" to support a rejection, and the action has no articulated reasoning with some rational underpinning to support the legal conclusion of obviousness (Remarks pages 6-7). However, the previous Office action provides such articulated reasoning with rational underpinning in the paragraph following the quoted statement. Specifically, the action states, "Klofta et al. thereby cure the deficiency of Hammons et al. by teaching the step of milling during dispersion of a substance in a lotion to be disposed on an absorbent product such as a sanitary napkin in order to break down particle size and disperse the particles, such that the average particle size is about 0.12 microns and the average agglomerate size is about 1.0 microns" (page 9). The action also states specific reasons supporting the legal conclusion of obviousness on page 13. The action also provides evidence in the form of citations to both Hammons et al. and Klofta et al. that support this articulated reasoning (pages 7-13).

Applicant argues that Klofta et al. does not teach or suggest a lotion comprising niacinamide (page 7). Although Klofta et al. does not specifically mention niacinamide, the primary reference, Hammons et al., does, as noted in the action (page 7).

Applicant argues that niacinamide is not typically considered to be an insoluble material, especially in comparison to a material such as zinc oxide, and that Klofta et al. does not teach or suggest appropriate particle size ranges for ingredients that are not insoluble (pages 7-8). However, this assertion is factually incorrect. Klofta et al. states, "The average particle size of the skin care ingredients should preferably be less than about 1000 microns, more preferably less than about 100 microns, and most preferably less than about 50 microns" (paragraph [0061]). Klofta et al. therefore does not limit the preferred average particle size to only insoluble skin care ingredients, as applicant asserts. Rather, Klofta et al. simply refers to "skin care ingredients," which would include soluble and insoluble skin care ingredients. Klofta et al. further teaches that solid particles in neat form tend to clump or agglomerate, and that it is often necessary to break up the clumps by, for example grinding or milling, to deliver skin benefits effectively (paragraph [0062]). Klofta et al. notably does not limit this teaching to only insoluble skin care ingredients. Thus, a person of ordinary skill in the art at the time the invention was made would learn from Klofta et al. that it is beneficial to grind or mill all skin care ingredients to prevent clumping and thereby deliver skin benefits effectively, wherein average particle sizes of the skin care ingredients are most preferably less than about 50 microns.

Furthermore, incorporating the teachings of Klofta et al. to make the composition of Hammons et al. can result in a premix composition that comprises zinc oxide, niacinamide, and glycerin, which is then added to the carrier system. Since the premix composition contains insoluble zinc oxide, it is advantageous to mill the premix composition according to the teachings of Klofta et al. Furthermore, such a premix composition that includes zinc oxide would be considered a "premix solution," as that term is used by applicant, since applicant refers to preparing lotion compositions "by formulating a premix solution of the zinc oxide skin treatment agent and adding the zinc oxide premix to the other skin treatment agents and any optional ingredients such as panthenol and glycerin, or by formulating a skin treatment solution of hexamidine and niacinamide skin treatment agents and any optional ingredients. The skin treatment solution is then added to a carrier system . . . ." (specification page 23; Examples II-IX). Thus, applicant clearly refers to a premix solution as including zinc oxide, and such "optional ingredients" could include zinc oxide.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL B. PALLAY whose telephone number is (571)270-3473. The examiner can normally be reached on Monday through Friday, 8:30 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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